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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/302,896	04/30/1999	MICHAEL B. CHANCELLOR	2710-4007-US	7603

7590 02/27/2002
MORGAN & FINNEGAN
345 PARK AVENUE
NEW YORK, NY 10154

EXAMINER

KAUSHAL, SUMESH

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 02/27/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/302,896

Applicant(s)

CHANCELLOR ET AL.

Examiner

Sumesh Kaushal

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-118 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-118 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

In response to applicant's arguments filed on Paper NO. 10, filed 12/15/01, the restriction requirement sent in an earlier Official Action on Paper NO. 8, 05/09/01 is vacated and a new restriction requirement is issued below.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-14, 43-48, 81, 83-91, 92-101, 102, 104, 106-116 drawn to a method of repairing genitourinary tract tissue comprising injecting genetically engineered muscle derived cells containing a heterologous gene, wherein the genitourinary tract dysfunction is Urinary stress incontinence, classified in class 424, subclass 93.21.
2. Claims 1-14, 43-48, 82-91, 92-101, 103, 105-114 and 117 drawn to a method of repairing genitourinary tract tissue comprising injecting genetically engineered muscle derived cells containing a heterologous gene, wherein the genitourinary tract dysfunction is Bladder inflammation, classified in class 424, subclass 93.21.
3. Claims 1-14, 49-55, 82-91, 92-101, 103, 105-114 and 117 drawn to a method of repairing genitourinary tract tissue comprising injecting genetically engineered muscle derived cells containing a heterologous gene wherein the genitourinary tract dysfunction is Erectile dysfunction, classified in class 424, subclass 93.21.
4. Claims 15-26 and 56-62 drawn to a method of repairing musculoskeletal tissue, comprising injecting genetically engineered muscle derived cells containing a heterologous gene, wherein the musculoskeletal tissue is degenerative arthritis, cartilage

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damage, meniscus damage, ligament damage joint damage or rheumatoid disease classified in class 424, subclass 93.21.

5. Claim 27-42 and 56-62, drawn to a method of repairing bone defect comprising injecting genetically engineered muscle derived cells into tissue surrounding bone containing a heterologous gene, wherein the bone defect is bone fracture, osteoporosis or osteosarcoma, classified in class 424, subclass 93.21.
6. Claims 63-68 are drawn to isolated genetically-engineered muscle-derived cells containing a heterologous gene encoding inducible *nitric oxide synthase gene*, classified in class 435, subclass 325.
7. Claims 69-75 are drawn to isolated genetically-engineered muscle-derived cells containing a heterologous gene encoding an *osteogenic protein gene*, classified in class 435, subclass 325.
8. Claims 76-80 and 118 are drawn to a method of isolating and purifying muscle-derived stem cells, classified in class 435, subclass 41.

The inventions are distinct, each from the other because of the following reasons:

Claims 10, 24, 40 and 114 are generic to a plurality of disclosed patentably distinct species comprising Acidic fibroblast growth factor, Basic fibroblast growth factor ... Insulin like growth factor, Nerve growth factor, Interleukins, Bone morphogenic proteins, Cartilage derived morphogenic proteins, ...Vascular endothelial growth factors and Sonic hedgehog proteins. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

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be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Inventions of Groups 1-3 are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention are drawn to method of repairing genitourinary tract tissue to treat a) Urinary stress incontinence b) Bladder inflammation and c) Erectile dysfunction. These defects have different sites in the urinary tract and have different modes of operation. For example, urinary stress incontinence is caused by dysfunctional sphincter muscle, Bladder inflammation leads to defects in bladder contraction, whereas erectile dysfunction is only limited to male population. The method of treatment would require different sites of action, which that have different functions. Therefore, these inventions are distinct and are of separate uses.

Inventions of Groups 1-3 are distinct from invention of Groups 4-5. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case these methods have different site of action in different organs in vivo that have different modes of operation. For example, urinary stress incontinence, bladder inflammation and erectile dysfunctions are only limited to genitourinary tract, whereas musculoskeletal tissue and bone defects are limited to skeletal muscles and the bones respectively. The method of treating genitourinary tract dysfunction is clearly distinct from treating a skeletal muscle or a bone disorder. For example, treating a urinary dysfunction would involves repair of sphincter muscle that open and control bladder neck, urethral muscle which regulates urodynamic and/or the bladder muscles that contract to empty the bladder during urination. These methods are is significantly different from the method of treating a bone fracture or a disease like muscular dystrophy, which have modes of operation, functions or effects. Thus, these inventions are distinct and are of separate uses.

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Inventions of Group 1-5 and Groups 6-8 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case besides cell mediated gene therapy the method of isolating and purifying muscle-derived stem cells could also be used to study the stem cell differentiation and characterization of isolated muscle stem cells. In addition, the genetically engineered muscle-derived cells could also be used to make recombinant proteins like iNOS or an osteogenic protein. Thus, these inventions are distinct and are of separate uses.

Because these inventions are distinct for the reasons given above and the search required for Group 1-3 is not required for Group 4-5, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is (703) 305-6838. The examiner can normally be reached on Monday-Friday from 9:00 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Irem Yucel can be reached on (703) 305-1998. The fax-phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst Zeta Adams, whose telephone number is (703) 305-3291.

If the claims are amended canceled and/or added the applicants are required to follow Amendment Practice under 37 CFR § 1.121 (<http://www.uspto.gov>) and A CLEAN COPY OF ALL PENDING CLAIMS IS REQUESTED.

S. Kaushal
Patent examiner

Scott D. Pribe
SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER